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DETAILED ACTION

Claims 1-7 are pending in this application.

Priority

This application is a National Stage application of PCT/US05/05247. The priority document has been forwarded by the International Bureau.

Information Disclosure Statement

The IDS filed 12/17/07 has been entered and considered.

Drawings

The drawings as filed are suitable to the Examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to methods of comparing data profiles. These methods are nonstatutory for at least the reasons below.

The methods do not require a particular machine or apparatus. They do not perform a transformation of matter. Further, the claims lack a practical application of the method and the result of the method. The resulting sets of the claims are not clearly useful. No tangible output is set forth.

As set forth in the recent decision *In re Bilski*, (In re Bilski, 88 USPQ at 1391,2008) "The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather

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than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See *Benson*, 409 U.S. ; *Diehr*, 450 U.S. at 192 ; see also *Flook*, 437 U.S. at 589 n.9 ; *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)".

The claims imply that the method is "computer implemented" or uses to a generic computer. The recitations of data profiles, as well as the limitations to comparing and deriving data imply the use of a computer.

As set forth in *In re Bilski*, the mere fact that a computer is present does not render the claim statutory. "*Benson* presents a difficult case under its own test in that the claimed process operated on a machine, a digital computer, but was still held to be ineligible subject matter. However, in *Benson*, the limitations tying the process to a computer were not actually limiting because the fundamental principle at issue, a particular algorithm, had no utility other than operating on a digital computer. *Benson*, 409 U.S. at 71-72. Thus, the claim's tie to a digital computer did not reduce the pre-emptive footprint of the claim since all uses of the algorithm were still covered by the claim" .

The claims recite limitations regarding "deriving a biological dataset profile" or "parameters resulting from exposure of cells to biological factors". These steps are merely data gathering, and do not meet the machine or transformation test outlined above.

Bilski: This court and our predecessor court have frequently stated that adding a data-gathering step to an algorithm is insufficient to convert that algorithm into a patent-eligible process. E.g., *Grams*, 888 F.2d at 840 (step of "deriv[ing] data for the algorithm will not render the claim statutory"); *Meyer*, 688 F.2d at 794 ("[data-gathering] step[s] cannot make an otherwise nonstatutory claim statutory")."

Bilski: "A requirement simply that data inputs be gathered—without specifying how—is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the gathering of data inputs. *Grams*, 888 F.2d at 839-40. Further, the inherent step of gathering data can also fairly be characterized as insignificant extra-solution activity."

The limitations of claims 4, 5 and 7 which purportedly contain a transformation of matter, are actually insignificant extra solution activity as defined in *In re Bilski*. These steps are not critical for the performance of the claimed method.

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In *Diehr*: "insignificant post solution activity will not transform an unpatentable principle into a patentable process." *Id.* at 191-92; see also *Flook*, 437 U.S. at 590 ("The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance.").

Bilski: "Even if a claim recites a specific machine or a particular transformation of a specific article, the recited machine or transformation must not constitute mere "insignificant post solution activity." Although the Court spoke of "post solution" activity, the Court's reasoning is equally applicable to any insignificant extra-solution activity regardless of where and when it appears in the claimed process. See *In re Schrader*, 22 F.3d 290, 294 (Fed. Cir. 1994) (holding a simple recordation step in the middle of the claimed process incapable of imparting patent-eligibility under § 101); *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir. 1989) (holding a pre-solution step of gathering data incapable of imparting patent-eligibility under § 101)."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 the metes and bounds of the steps to provide the characterization are unclear. It is unclear what parameters are to be obtained and what the asthma/atopy context system comprises. It is unclear how to derive a dataset from these parameters. It is further unclear whether the profile of the first steps is the same profile being modified in the second step (control) and the same profile in the third step (agent). It would appear that these would need to be separate profiles, but that isn't clearly stated. It is further unclear how significant any difference needs to be. It is unclear how these steps meet the goal of "characterizing a candidate

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agent for activity”. It is unclear if the “candidate agent “ and the “test agent” both recited in claim 1 are the same agent.

The metes and bounds of the term “genetic agent” in claim 2 are unclear. Limitations from the specification cannot be read into the claims. How does this differ from the “biological agent” of claim 3?

It is unclear which profile is being referenced by claim 4. It is unclear what parameters are to be used, what cells, what biological factors etc. It is unclear what a biological factor is, and how it differs from the "biological agent" of claim 3. Is the test agent of claim 4 the same agent that is in claim 1?

The limitations of claim 5 are unclear, as it is unclear how the data system of claim 1 is intended to comprise samples. It is unclear what constitutes a “common biologically relevant context” and what the “control” comprises.

It is similarly unclear how to “concatenate” the data system of claim 1, or how the samples of claim 5 are to be concatenated.

It is unclear if claim 7 is intended to modify the asthma/atopy context system of claim 1, or some other context. It is further unclear how the primary cells further limit the data systems.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by BERG et al. US 6,656,695.

Berg et al disclose method of characterization of agents using the Biomap system of the instant specification. Asthma and Atopy context systems are specifically described at col 32-35. Profiles of the asthma/atopy context are derived in the absence of, and in the presence of a candidate agent, and various parameters are compared. Various types of agents are disclosed including biological and chemical. Bronchial cell, mast cell and Th2 T cells are disclosed. As such, the rejected claims are anticipated.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by BERG et al. US 2003/017445.

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Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by BERG et al. US 2003/0113807.

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Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by PLAVEC et al. US 7266458.

PLAVEC et al disclose method of characterization of agents using the Biomap system of the instant specification. Asthma and Atopy context systems are specifically described throughout. Profiles of the asthma/atopy context are derived in the absence of, and in the presence of a candidate agent, and various parameters are compared. Various types of agents are disclosed including genetic, biological and chemical. Bronchial cell, mast cell and Th2 T cells are disclosed. As such, the rejected claims are anticipated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Mary K Zeman/

Primary Examiner, Art Unit 1631